K100794

JAN 25 2011

SECTION 5 – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

APPLICANT: Dr. Sarah Pollington

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CONTACT PERSON: Dr. Sarah Pollington

OFFICIAL CORRESPONDENT: Ms. Judy Burton, Advena Ltd.

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DATE OF SUMMARY: November 19, 2010

TRADE NAME: Fluorcanasite Dental Ceramic

COMMON NAME: Dental Ceramic

CLASSIFICATION NAME: Porcelein Powder for Clinical Use

CLASSIFICATION CODE: EIH

REGULATION NO.: 872.6660

PREDICATE DEVICE: K051705 IPS E. Max CAD

CLASSIFICATION CODE: EIH

REGULATION NO.: 872.6660

DEVICE DESCRIPTION: Fluorcanasite is a CAD/CAM machinable glass ceramic block, batched from standard glass-making ingredients which are intended to be used by trained professionals in a dentist's office for the manufacture of all-ceramic inlays, onlays, crowns, and veneers.

DEVICE COMPARISON:

	New Device	Predicate Device
510(k) Number		K051705
Device Name, Model	Fluorcanasite	IPS e. max CAD (lithium disilicate)
Manufacturer	Dr. Sarah Pollington	Ivoclar Vivadent, Inc.
Intended Use	A ceramic material to be used for machining into tooth cores that are then veneered and secured by a specific adhesive to the dentine of a patient's modified and prepared tooth.	IPS e. max CAD is a CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of full ceramic crowns, inlays, onlays, and full ceramic 3-unit anterior bridges.
Biaxial flexural strength	271.3 MPa	360 MPa
CTE	8.8 ppm/°C	10.45 ppm/°C
Chemical solubility	722 ug/cm^2	30-50 ug/cm^2
Fracture toughness	4.2 MPa m$^{1/2}$	2.0-2.5 MPa m$^{1/2}$
Hardness	5.18 GPa	5.94 GPa
MTBS (ceramic composite)	27.59 MPa	n/a

INTENDED USE: Fluorcanasite is a CAD/CAM machinable glass ceramic block, batched from standard glass-making ingredients which are intended to be used by trained professionals in a dentist's office for the manufacture of all-ceramic inlays, onlays, crowns, and veneers.

TECHNOLOGICAL CHARACTERISTICS: Fluorcanasite is a multiple chain-silicate glass-ceramic comprised of sodium carbonate, potassium carbonate, calcium carbonate, calcium fluoride, Loch Aline sand (high purity silica) and zirconia. Its properties display high strength and fracture toughness and the potential as an indirect resin-bonded dental restoration.

CLINICAL TESTING: Non-clinical test data was used to support the devices safety and effectiveness.

NON-CLINICAL TESTING: Fluorcanasite was subjected to the following non-clinical testing:

- ISO 6872:2008: Biaxial Flexural Strength, Fracture Toughness and Clinical Solubility;
- Vickers Hardness: Thermal Shock, Hardness and Brittleness Index, and Shelf Life;
- ISO 10993-5: Biocompatibility; and,
- XRD and SEM – Crystalline Phase and Microstructural Analysis

with the result that Fluorcanasite performed as well as, or better than, the predicate device.

OTHER INFORMATION DEEMED NECESSARY BY FDA: A sample of dental restorative glass powder was analysed for uranium content. The results of the radiochemical analysis are tabulated on the following, with uncertainties quoted with a coverage factor of *k=2*, providing a level of confidence of approximately 95%. This work was managed under the NPL LRQA registration to ISO 9001:2000.

Uranium was measured in this sample by initial dissolution in mineral acids, followed by ion exchange separation of uranium. The separated uranium was electrodeposited onto a stainless steel disc, which was then measured using α-particle spectrometry. Standardised ^{232}U was added as a chemical yield tracer for the analysis.

NPL identifier	Nuclide	Activity concentration Bq/kg	*Mass concentration*[1] *µg/kg*
IM0900	^{234}U	<8	*<0.035*
	^{235}U	<1	*<0.51*
	^{238}U	<1	*<6.5*
	Total	<10	*<7.0*

CONCLUSION:

The testing indicates that Fluorcanasite is safe and effective for its intended use and performs as well or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Sarah Pollington
C/O Ms. Judy Burton
Advena Limited
3010 LBJ Freeway, 12th Floor
Dallas, Texas 75234

JAN 25 2011

Re: K100794
Trade/Device Name: Fluorcanasite Dental Ceramic
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: January 14, 2011
Received: January 21, 2011

Dear Ms. Burton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K100794

Device Name: Fluorcanasite Dental Ceramic

Fluorcanasite is a CAD/CAM machinable glass ceramic block, batched from standard glass-making ingredients which are intended to be used by trained professionals in a dentist's office for the manufacture of all-ceramic inlays, onlays, crowns, and veneers.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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